

**II. The Rejection Under 35 U.S.C. § 101**

In the Office Action, at pages 3-5, the Examiner has maintained the rejection of claims 1, 2, and 7-17, because the claimed invention is allegedly not supported by either specific and/or substantial utility or a well established utility as outlined in the Revised Interim Utility Guidelines Training Materials ("Interim Guidelines"). Applicants respectfully disagree with this assertion.

In support of the position that the claimed nucleic acid molecules lack substantial utility, the Examiner states that "[a]bsent factual evidence, a percentage sequence similarity of less than 100% is not deemed to reasonably support to one skilled in the art whether the biochemical activity of the claimed subject matter would be the same as that of such a similar known biomolecule." Office Action at page 4. The Examiner asserts that "[s]everal publications document the unpredictability of the relationship between sequence, structure, and function, although it is acknowledged that certain specific sequences have been found to be conserved in biomolecules having related function following a significant amount of further research." Office Action at page 4.

Applicants respectfully disagree and refer the Examiner to the following articles, copies of which are enclosed for the Examiner's convenience, where sequence similarity is routinely used by those of ordinary skill in the art as a predictor of function. *See, e.g., Venter, et al., The Sequence of the Human Genome, Science, 291: 1304-1351 (2001); Woese, et al., Conservation of Primary Structure in 16S rRNA, Nature, 254: 83-85 (1975).* Accordingly, Applicants maintain that one of ordinary skill in the art would have recognized, in light of Applicants' teachings, that at the time of filing Applicants had possession of the claimed invention for the uses described in the specification.

In view of the foregoing, Applicants contend that the claimed nucleic acid molecules are supported by specific and substantial utilities disclosed in the specification. Consequently, sustaining the rejection of claims 1, 2, and 7-17 under 35 U.S.C. §101 is improper. Reconsideration and withdraw are respectfully requested.

**III. Rejection Under 35 U.S.C. § 112, First Paragraph, Enablement**

In the Office Action, at pages 5 and 6, the Examiner has maintained the rejection of claims 1, 2, and 7-17 as not being enabled by the specification, because the claimed invention allegedly lacks utility. Applicants respectfully traverse this rejection. This rejection has been overcome by the foregoing arguments regarding utility. Therefore, the rejection under 35 U.S.C. § 112, first paragraph, is improper. Reconsideration and withdraw are respectfully requested.

**IV. Rejection Under 35 U.S.C. § 112, First Paragraph, Written Description**

In the Office Action, at pages 6 and 7, the Examiner has maintained the rejection of claims 1, 2, and 7-17 as allegedly lacking an adequate written description. The Examiner acknowledges that the specification discloses the claimed SEQ ID NOs. However, the Examiner argues that “specific embodiments of the claims are directed to the encoding sequence for various enzymes” and that “[a]pplicants have not supplied any structural information that extends the sequences in the claims to these full enzyme coding regions”. Office Action at pages 6-7.

Applicants respectfully disagree. First, Applicants point out that claims 7-17 are directed to substantially purified nucleic acid molecules comprising a nucleic acid sequence selected from the group consisting of SEQ ID NOs: 11, 446, 935, 1108, 2042, 2166, 2252, 2644, 2681, and 2753. Applicants submit that the specification provides an adequate written description of the claimed invention. Adequate written description of a claimed genus can be achieved by “recitation of structural features common to the members of the genus.” *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997). Furthermore, adequate written description merely requires that “[t]he feature relied upon to describe the claimed genus must be capable of distinguishing members of the claimed genus from non-members.” *Id* (emphasis added). Thus, the specification provides adequate written description for the claimed invention because, features of the claimed substantially purified nucleic acid molecule genus, for example, the recited nucleotide sequences, distinguish the

claimed genus from unclaimed purified nucleotide molecules, which do not include the recited nucleotide sequences.

Furthermore, as noted in Applicants' November 14, 2001 Amendment and Reply, the fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed through the present specification. Moreover, the specification discloses embodiments of the claimed invention in which nucleotide sequences of the claimed nucleic acid molecules can be combined with promoters and other genetic elements including but not limited to transcriptional regulatory elements, which can include a full-enzyme coding region. *See, e.g.*, specification at page 75, line 15 to page 77, line 14 and page 84, line 16 to page 85, line 19. Thus, one of ordinary skill in the art could have envisioned the claimed invention based on the specification, and the specification provides adequate written description for the claimed invention. Therefore, this rejection is improper and should be withdrawn.

#### ***V. The Objection to the Specification***

In the Office Action at page 7, the Examiner has made objections to the specification because the specification allegedly contains hyperlinks and/or other forms of browser-executable code. Applicants have previously accommodated this objection by amendment of the specification to remove all "http://" prefixes, underlining, and embedded hyperlinks. *See* Responsive Amendment filed November 14, 2001.

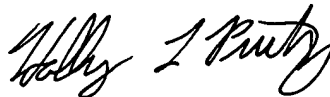
A URL is not considered to be browser executable code if it is not either preceded with *http://* or placed between the symbols "<>." M.P.E.P. § 608.01, page 600-60, Examiner Note. As such, the URLs present in the application, as amended, are not browser executable code, and would not be interpreted by a browser as a link to another web site when the document is placed on the USPTO web site. Reconsideration and withdrawal of this objection are respectfully requested.

**VI. Summary**

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided. Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

It is not believed that extensions of time are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 50-1824, referencing matter number 16517.228.

Respectfully submitted,



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